August 14, 2017

Anthera Pharmaceuticals Announces RESULT Phase 3 Clinical Study of Sollpura will be Included in the European Cystic Fibrosis Clinical Trial Network

HAYWARD, Calif., Aug. 14, 2017 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals (Nasdaq:ANTH) today announced that the RESULT Phase 3 clinical study of Sollpura for exocrine pancreatic insufficiency due to cystic fibrosis has been approved by the European Cystic Fibrosis Society Clinical Trial Network (ECFS CTN) Executive Committee. The aim of the ECFS CTN is to intensify clinical research in the area of cystic fibrosis and to bring new medicines to patients as quickly as possible. Enrollment in RESULT, in both the US and EU, is on schedule and inclusion of the study in the ECFS CTN may further expedite patient recruitment for the RESULT clinical study. Topline data are expected at the end of 2017 to early 2018, depending on the speed of patient enrollment.

"We are very pleased to receive approval by the ECFS Executive Committee for inclusion of the RESULT trial in the ECFS CTN," said Craig Thompson, President & CEO of Anthera. "This achievement, in combination with the earlier approval from the Cystic Fibrosis Foundation Therapeutics Development Network, represents another key milestone for the RESULT trial."

The RESULT clinical study design evolved from the data in the previous Sollpura trial (SOLUTION) and allows for more frequent and higher dose adjustments based upon clinical signs and symptoms. As with current practice with porcine enzymes, the RESULT study allows dose increases on an individualized basis to achieve maximum therapeutic benefit, while maintaining a potential reduction in daily pill burden due to Sollpura's significantly more compact formulation technology.

About RESULT

The Phase 3 RESULT study is designed to evaluate the non-inferiority of Sollpura at individualized doses compared to approved, porcine-derived, enteric-coated pancreatic enzyme replacement therapy (PERT) when administered to patients with EPI due to CF. The study will enroll patients (N≈150) who are well-controlled on stable porcine PERT at screening, as demonstrated by the coefficient of fat absorption (CFA). The primary efficacy variable will evaluate the change from baseline in CFA following 4 weeks of treatment with either Sollpura or Pancreaze. Patients randomized to Sollpura will then be followed for an additional 20-Week extension period (total of 24 weeks on study) for longer term assessments of weight, height, BMI, and safety.

About Sollpura® (liprotamase)

Sollpura is a novel, non-porcine PERT containing a proprietary, biotechnology-derived formulation of cross-linked crystalline lipase, crystalline protease, and amorphous amylase with broad substrate specificity, formulated in a precise and fixed ratio to provide stability in acidic pH environments, like that found in the stomach, without enteric coating. Being non-porcine, Sollpura mitigates porcine-associated risks including supply limitations and the potential for contamination with pig-associated viral or other infectious agents. In addition, given its stability in the absence of enteric coating, a soluble, drinkable formulation of Sollpura is in development, which may provide an easy-to-administer option especially for pediatric patients and patients who receive their nutrition through feeding tubes.

About Anthera Pharmaceuticals, Inc.

Anthera Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing products to treat serious and life-threatening diseases, including exocrine pancreatic insufficiency and IgA nephropathy. Additional information on Anthera can be found at www.anthera.com.

Safe Harbor Statement

Any statements contained in this press release that refer to future events or other non-historical matters, including statements that are preceded by, followed by, or that include such words as "estimate," "intend," "anticipate," "believe," "plan," "goal," "expect," "project," or similar statements, are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on Anthera's expectations as of the date of this press release and are subject to certain risks and uncertainties that could cause actual results to differ materially as set forth in Anthera's public filings with the SEC, including Anthera's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017. Anthera disclaims any intent or obligation to update any forward-looking

statements, whether because of new information, future events or otherwise, except as required by applicable law.

Contact Information

CONTACT: Investor Relations of Anthera Pharmaceuticals, Inc.
ir@anthera.com

For Media Inquiries:
Frannie Marmorstein
rbb Communications
frannie.marmorstein@rbbcommunications.com
305-567-0821

www.twitter.com/antherapharma
https://www.facebook.com/antherapharma/
https://www.linkedin.com/company/anthera-pharmaceuticals


Primary Logo

Source: Anthera Pharmaceuticals, Inc.